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Vita G. Conforti, Reg. No. 39,639

Name of Applicant, assignee or  
Registered Representative

Vita Conforti  
Signature

35 signature

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Francisco et al.	
Serial No.: 09/724,406	Group Art Unit: 1642
Filed: November 28, 2000	Examiner: Yu, Misook
For:	RECOMBINANT ANTI-CD30 ANTIBODIES AND USES THEREOF

**AFFIDAVIT OF DR. JOSEPH A. FRANCISCO  
UNDER 37 CFR § 1.132**

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Joseph A. Francisco, do declare and state that:

1. I am a citizen of the United States residing at 22701 N. Deer Drive, Woodway, Washington, 98020.
2. I am an inventor of the invention described and claimed in the above identified patent application Serial No. 09/724,406.

3. From 1998 to the present, I have been at Seattle Genetics, Inc. assignee of the above identified application, initially as a Principal Scientist (from 1998 to 2000) and presently as Director of Preclinical Development. From 1997 to 1998, I was a Scientist at Monsanto in Saint Louis, Missouri. From 1994 to 1997 I was at Bristol-Myers Squibb Pharmaceutical Research Institute, Seattle, Washington, first as a Post-doctoral Fellow, (1994-1996), then as a Research Investigator (1997). I received the degree of Doctor of Philosophy from the University of Texas at Austin in Chemical Engineering in 1994.
4. My academic and technical experience and honors, and a list of my publications are set forth in my curriculum vitae, attached hereto as Exhibit 1.
5. I have reviewed WO 96/22384 (Lemke).
6. Upon my review of Lemke, Lemke does not provide any data or experiments to show an antibody that exerts a cytostatic or cytotoxic effect on the Hodgkin's Disease cell line in the absence of conjugation to a cytostatic or cytotoxic agent as claimed in claim 1 of the instant application.
7. It is known to one of ordinary skill in the art that not all naked antibodies have cytostatic or cytotoxic properties.
8. I have reviewed the article by Schnell et al., "Development of New Ricin A-Chain Immunotoxins with Potent Anti-Tumor Effects Against Human Hodgkin Cells *in Vitro* and Disseminated Hodgkin Tumors in SCID Mice Using High-Affinity Monoclonal Antibodies Directed Against the CD30 Antigen," *Int. J. Cancer* 63:238-244 (1995).
9. Schnell et al generally describe the following experiment using Ki-4 on page 241, left column, under "Cytotoxicity of new CD30 ricin A-chain ITs against Hodgkin cells":
  - a. CD30 antibodies were screened for their effectiveness in indirect assays against L540Cy Hodgkin cells, with Ki-4 being very potent for specificity.

b. The MAbs were coupled via SMPT to deglycosylated ricin A-chain.

c. The cytotoxicity was evaluated in standard [<sup>3</sup>H]-leucine uptake assays.

d. The naïve antibodies were not toxic at 10<sup>-6</sup> M.

10. Schnell *et al* state on page 241, left column, lines 29-31, that the cytotoxicity of the immunotoxins was specific yet the naïve antibodies *were not toxic*.

11. Schnell *et al* state on page 241, right column, lines 10-13, that treatment with Ki-4 did not induce complete remission.

12. Upon my review of Schnell *et al*, of which Dr. Hilmar Lemke listed as an inventor on WO 96/22384 is also an author, it would be known to one of skill in the art, at least as of the publication date of Schnell *et al* and prior to the filing date of the instant application, that Lemke's exemplary naked antibody, Ki-4, does not have cytotoxic or cytostatic activity.

13. I declare further that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated:

7/15/04

Joseph A. Francisco

Attachments:

Exhibit 1: Cirriculum Vitae of Joseph A. Francisco

Exhibit 2: Schnell *et al.*, "Development of New Ricin A-Chain Immunotoxins with Potent Anti-Tumor Effects Against Human Hodgkin Cells *in Vitro* and Disseminated Hodgkin Tumors in SCID Mice Using High-Affinity Monoclonal

Antibodies Directed Against the CD30 Antigen," *Int. J. Cancer* 63:238-244  
(1995).